

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
This document relates to: Ethicon Wave 1 cases listed in Exhibit A of Plaintiffs' Motion	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE
LIMIT THE OPINIONS AND TESTIMONY OF SCOTT SERELS, M.D.**

Certain Wave 1 Plaintiffs offer the following Reply in Support of their Motion to Exclude or Otherwise Limit the Opinions and Testimony of Scott Serels, M.D.:

I. ARGUMENT

A. Dr. Serels should not be permitted to offer opinions on mesh design generally or the effects of the TVT design on the general population.

In its Response [Doc. 2226], Ethicon first appears to concede that Dr. Serels is unqualified to speak to the intricacies of mesh design: "His opinions are related more to the efficacy of the device than a *per se* design opinion." *See* Response, at 4. Nonetheless, Ethicon maintains that, given his experience, Dr. Serels should be permitted to testify that "in his hundreds of uses of these products, the design was efficacious in treating difficult pelvic floor disorders." *See* Response, at 5.

Certainly Dr. Serels is not unqualified to speak to his own patient's outcomes, but his Report attempts to stretch this personal experience globally: "the TVT's design and material is

reasonably safe for its intended use.” See Ex. C, § I.9.¹ This *ipse dixit* is not a proper basis for expert testimony. See *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 701 (S.D. W. Va. 2014). Dr. Serels’s opinions about TVT design generally should therefore be excluded.

B. Dr. Serels should not be permitted to discuss mesh degradation and particle loss.

Next, Ethicon notes that this Court previously permitted degradation testimony similar to that offered by Dr. Serels, based on “personal experience and [a] review of medical literature.” See Response, at 5-6 (citing *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 734-35 (S.D. W. Va. 2014)). But *Huskey* is distinguishable, and, in any event, not definitive. See *Wilkerson v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 58671 (S.D. W. Va. 2015) (“[C]ounsel’s expectations that I align with these previous rulings when faced with a different record are remiss[.]”); see also *Mathison v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 59047 (S.D. W. Va. 2015) (“I am informed—though not bound—by my previous findings.”).

Ethicon does not address Plaintiffs’ twin arguments concerning Dr. Serels’s review of medical literature. First, Ethicon leaves unanswered Plaintiffs’ contention that Dr. Serels’s opinions are unreliable, because they are based on irrelevant information or plainly undermined by his deposition testimony. See Memorandum in Support [Doc. 2113], at 7. Secondly, Ethicon does not respond directly to the argument that Dr. Serels failed to consider contrary scientific literature. See *id.* at 9-10. In a separate section of its Response, Ethicon notes that “failure to review or cite particular documents [] goes to the weight of his opinion, not its admissibility, and can be addressed on cross-examination.” See Response, at 7 (quoting *Sanchez v. Boston Scientific Corp.*, 2014 U.S. Dist. LEXIS 137189 at *78 (S.D.W.V. Sept. 29, 2014)).

¹ Citations to exhibits refer to those exhibits attached to Plaintiffs’ original motion.

In *Sanchez*, however, the expert did not admit to failing to consider contrary evidence (or state that the entirety of his preparation lasted only “three or four hours”) and then discount that evidence due to his “unwavering” personal opinions. *See* Memorandum in Support, at 1, 9-10. Further, Dr. Serels provided no explanation for why the documents discussed by Plaintiffs’ experts should be discounted, aside from the fact that his “expert opinion is pretty unwavering based on [his] expertise.” *Cf. Tyree v. Boston Scientific Corp.*, 54 F.Supp.3d 501, 520-21, 559 (S.D. W. Va. 2014) (excluding one expert for failing to provide an adequate basis for discounting certain documents, while admitting another expert who offered a proper explanation). His opinions should be excluded accordingly.

C. Dr. Serels should not be permitted to testify regarding the significance of laser-cut versus mechanically cut mesh.

Ethicon’s response to Plaintiffs’ challenges with respect to cutting processes is largely the same as its response regarding degradation. *See* Response, at 6. Again, Ethicon ignores the fact that Dr. Serels admitted repeatedly that he has no qualifications to opine on cutting techniques, nor any reliable basis for discussing the clinical effects or lack thereof. *See* Memorandum in Support, at 5-8. *Even among his own patients*, Dr. Serels has no method for identifying the type of mesh implanted or the particular effects experienced by those patients. *See id.*

Further, this is not a situation where an expert merely failed to review a document or two. Dr. Serels knows nothing about laser-cut versus mechanically cut mesh; by all indications, he has never seen a document of any kind discussing the two types of mesh, let alone the documents cited by Plaintiffs’ experts. *See id.* at 6, 10. His opinions on the subject should be excluded.

D. Dr. Serels should not be permitted to offer opinions regarding cytotoxicity.

Again, on the issue of cytotoxicity, Ethicon argues that Dr. Serels’s boilerplate statements that he reviewed unnamed literature make him qualified and provide a reliable basis for his

opinions. *See* Response, at 6-7. Ethicon fails to address the fact that Dr. Serels is unfamiliar with even the basic process of testing for cytotoxicity, as well as the fact that Dr. Serels does not know one way or the other whether certain raw materials (like polypropylene) affect the human body differently than other raw materials. *See* Memorandum in Support, at 4-7. His opinions on cytotoxicity should be excluded.

E. Dr. Serels should not be permitted to discuss the adequacy of the TVT Instructions for Use.

As with design issues, Ethicon concedes that Dr. Serels cannot reliably offer certain opinions regarding IFUs, and argues instead that Dr. Serels's IFU opinions are actually supposed to be quite limited: Dr. Serels "opines that pelvic surgeons would have known that these risks exist just in performing pelvic surgery" and that the IFU was therefore "adequate" in every case. *See* Response, at 11.

This is fact-finding masquerading as expert testimony. Whether a particular risk was known to an implanting physician is an issue for a jury to decide. Dr. Serels cannot offer the opinion that every reasonable pelvic surgeon knew certain risks, and that the contents of the IFU are therefore irrelevant in every case.

Even assuming this was a proper area for expert testimony, Dr. Serels is both unqualified to offer the opinion and has no reliable basis for doing so. Once more, Ethicon does not address the issues with Dr. Serels's deposition testimony—in particular Dr. Serels's admissions that he has made no effort to confirm that his understanding of what needs to be in an IFU is in fact consistent with that of other pelvic surgeons, and that his IFU opinions are subjective. *See* Memorandum in Support, at 12-13. His IFU testimony should be excluded accordingly.

F. Dr. Serels should not be permitted to testify regarding the risks associated with traditional SUI repairs.

Ethicon then argues that “[t]here can be no question that Dr. Serels’s opinions regarding the existence of complications and relative safety of the TVT system when compared to alternative methods are well-supported by his education, clinical experience, and medical literature review.” *See* Response, at 12. This general statement fails—just as Dr. Serels’s report fails—to explain the basis for Dr. Serels’s highly specific opinions that various complications are “not unique” to Prolene mesh and that the TVT “appears safer” than other repair options. *See* Memorandum in Support, at 14. Those opinions should be excluded.

G. Dr. Serels should not be permitted to offer legal conclusions and prejudicial statements.

Ethicon states without explanation or citation to authority that phrases like “reasonably safe for its intended use,” “adequately and appropriately warns,” and “reasonably prudent pelvic floor surgeon should know,” are not legal conclusions. *See* Response, at 12. This is contrary to this Court’s comments in *Wise*:

I note that some portions of Dr. Ostergard’s expert report seem to go a step further than comparing the risks of the product to the content of the label. For instance, Dr. Ostergard opines that the purported omissions in the Avaulta IFU “rendered [the device] not reasonably safe.” (Ostergard Report [Docket 113-1], at 11). This opinion invades the province of the jury by stating a legal conclusion and will not be accepted at trial. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); see also *Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008) (precluding an expert witness “from using legal terms of art” and “giv[ing] legal conclusions, such as, but not limited to, the conclusions that the [product] was ‘defective,’ ‘unreasonably dangerous,’ or was the ‘proximate cause’ of [the plaintiff’s] injury”).

Wise v. Bard, No. 2:12-cv-01378, n. 4 (S.D. W. Va., Feb. 7, 2015) (*Daubert* orders). As such, Dr. Serels’s legal conclusions should be excluded.

Finally, Ethicon notes that Dr. Serels will not offer some of the inflammatory statements contained in his Report. *See* Response, at 13. However, Ethicon maintains that he will offer the opinion that “the polypropylene mesh sling is important to the treatment of SUI and women’s health in general.” *See id.* As stated in Plaintiffs’ Memorandum in Support, this is not expert testimony—it is a transparent attempt to frighten a jury away from entering judgment against a medical device manufacturer. *See* Memorandum, at 15. Those comments should be excluded.

II. CONCLUSION

For these reasons and for the reasons offered in Plaintiffs’ original motion, Plaintiffs respectfully request that this Court grant their motion and exclude or otherwise limit the opinions and testimony of Dr. Serels.

Dated: May 23, 2016

Respectfully submitted,
Wave 1 Plaintiffs

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of May, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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